IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAYNE PHARMA INTERNATIONAL PTY LTD,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
ACTAVIS ELIZABETH LLC and TEVA PHARMACEUTICALS USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mayne Pharma International Pty Ltd ("Mayne" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendants Actavis Elizabeth LLC ("Actavis Elizabeth") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Defendants"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendants' recent submission to the United States Food and Drug Administration ("FDA") of a Prior Approval Supplement to Abbreviated New Drug Application ("ANDA") No. 090134 (hereinafter, the "Supplement"). Through the Supplement, Defendants seek approval to market generic versions of Mayne's pharmaceutical product DORYX® MPC (doxycycline hyclate delayed-release tablets), 60 mg and 120 mg, prior to the expiration of United States Patent No. 6,958,161 ("the '161 Patent"); United States Patent No. 9,295,652 ("the '652 Patent"); United States Patent No. 9,446,057 ("the '057 Patent"); and United States Patent No. 9,511,031 ("the '031 Patent"). Plaintiff seeks injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

2. Plaintiff Mayne Pharma International Pty Ltd is a corporation organized and existing under the laws of the Commonwealth of Australia, with a place of business at 1538 Main North Road, Salisbury South, SA 5106, Australia. Mayne is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. On information and belief, Defendant Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

5. On information and belief, Actavis Elizabeth LLC is an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.

6. On information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products.

7. On information and belief, Defendants collaborated in the preparation and submission of the Supplement and continue to collaborate in seeking FDA approval of that supplement.

8. On information and belief, Defendants intend to collaborate in the commercial manufacture, marketing, offer for sale, and sale of the 60 mg and 120 mg doxycycline hyclate products described in the Supplement (hereinafter, "Defendants' ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves Defendants' ANDA Products.

9. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Defendants' ANDA Products, and enter into agreements with each other that are nearer than arm's length.

10. On information and belief, Teva participated in, assisted, and cooperated with Actavis Elizabeth in the acts complained of herein.

JURISDICTION AND VENUE

11. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '161 Patent, the '652 Patent, the '057 Patent, and the '031 Patent.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

13. This Court has personal jurisdiction over Actavis Elizabeth because, *inter alia*, on information and belief it is a limited liability company organized and existing under the laws of the State of Delaware.

14. This Court has personal jurisdiction over Teva because, *inter alia*, on information and belief it is a corporation organized and existing under the laws of the State of Delaware.

15. This Court also has personal jurisdiction over Defendants because each Defendant has continuous and systematic contacts with the State of Delaware. On information and belief, Defendants regularly conduct business in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. On information and belief, Defendants receive Medicaid reimbursements for drugs sold in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or

agents. On information and belief, Defendants do business in the State of Delaware through a permanent and continuous presence there. On information and belief, Defendants and/or their subsidiaries in the State of Delaware develop, manufacture, and/or market generic and proprietary pharmaceuticals. On information and belief, Defendants and/or their subsidiaries actively seek employment of sales representatives to serve customers in the State of Delaware, continuously employ sales representatives in the State of Delaware, and regularly market their products in the State of Delaware.

16. This Court also has personal jurisdiction over Defendants because each Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures DORYX® MPC for sale and use throughout the United States, including this judicial district. On information and belief and as stated in a letter dated September 28, 2017 sent by Teva to Mayne pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), Defendants prepared and filed the Supplement with the intention of seeking to market Defendants' ANDA Products nationwide, including within this judicial district. On information and belief, Defendants plan to sell Defendants' ANDA Products in the State of Delaware, list Defendants' ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of Defendants' ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries and/or agents. The activities described in paragraph 15 and this paragraph satisfy due process and confer personal jurisdiction over Defendants consistent with the laws of Delaware. *See, e.g.*, *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016) (holding that minimum-contacts requirement for specific personal jurisdiction is established where the defendant's "ANDA filings and its distribution channels

establish that [the defendant] plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about patent constraints on such in-State marketing").

17. This Court also has personal jurisdiction over Defendants because each Defendant regularly engages in patent litigation concerning FDA-approved branded drug products in this judicial district, does not contest personal jurisdiction in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Biogen Int'l GmbH v. Teva Pharm. USA, Inc.*, 17-cv-00829, D.I. 10 (D. Del. Oc. 16, 2017); *Orexo AB v. Actavis Elizabeth LLC*, 17-cv-00758, D.I. 11 (D. Del. July 21, 2017); *Onyx Therapeutics, Inc. v. Teva Pharm. USA, Inc.*, 17-cv-00449, D.I. 9 (D. Del. May 17, 2017); *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, 16-cv-00905, D.I. 16 (D. Del. Dec. 16, 2016); *Tris Pharma, Inc. v. Actavis Elizabeth LLC*, 16-cv-00603, D.I. 9 (D. Del. Sept. 2, 2016); *Novartis AG v. Actavis, Inc.*, 14-cv-01487, D.I. 13 (D. Del. Feb. 6, 2015).

18. Venue is proper in this district for Actavis Elizabeth pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief Actavis Elizabeth is a limited liability company organized and existing under the laws of the State of Delaware.

19. Venue is proper in this district for Teva pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief Teva is a corporation organized and existing under the laws of the State of Delaware.

20. In the alternative, venue is proper in this district for Defendants because, on information and belief, each Defendant has committed acts of infringement and has a regular and established place of business in this district. *See, e.g., Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 17-CV-379-LPS, 2017 WL 3980155, at *13 (holding that "an applicant's submission of an ANDA, in conjunction with other acts the ANDA applicant non-speculatively intends to

take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District, . . . can be sufficient to demonstrate that the ANDA-filing Defendant 'has committed' 'acts of infringement' in this District"). On information and belief, each Defendant is part of a family of companies all of which ultimate corporate parent is Teva Pharmaceutical Industries Limited. On information and belief, the family of companies includes at least thirty U.S. subsidiaries that are incorporated under the laws of the State of Delaware. On information and belief, the family of companies leverages a broad network of local and global access channels in order to get its generic drugs to customers in the State of Delaware. The activities described in paragraphs 15 through 17 and this paragraph amount to a regular and established place of business sufficient to confer venue.

MAYNE'S APPROVED DORYX® MPC DRUG PRODUCT AND PATENTS

21. Mayne is the holder of New Drug Application ("NDA") No. 050795 for DORYX® tablets (50 mg, 75 mg, 80 mg, 100 mg, 150 mg, and 200 mg dosage strengths) and DORYX® MPC tablets (60 mg and 120 mg dosage strengths), each of which contains the active ingredient doxycycline hyclate. FDA first approved NDA No. 050795 for tablets containing 75 mg and 100 mg dosage strengths on May 6, 2005. FDA approved a supplement to NDA No. 050795 for tablets with a modified polymer coat (MPC) and containing 60 mg and 120 mg dosage strengths on May 20, 2016. DORYX® MPC is an oral antibacterial drug prescribed for several indications including, but not limited to, spotted and typhus fevers, anthrax, and severe acne. A true and correct copy of the current FDA-approved Prescribing Information for DORYX® MPC, covering both the 60 mg and 120 mg dosage strengths, is attached hereto as Exhibit A.

22. Mayne owns the '161 Patent, the '652 Patent, the '057 Patent, and the '031 Patent.

23. The ’161 Patent, the ’652 Patent, the ’057 Patent, and the ’031 Patent are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for DORYX® MPC, 60 mg and 120 mg.

24. The ’161 Patent, entitled “Modified Release Coated Drug Preparation,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on October 25, 2005. A true and correct copy of the ’161 Patent is attached hereto as Exhibit B.

25. The ’652 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the USPTO on March 29, 2016. A true and correct copy of the ’652 Patent is attached hereto as Exhibit C.

26. The ’057 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the USPTO on September 20, 2016. A true and correct copy of the ’057 Patent is attached hereto as Exhibit D.

27. The ’031 Patent, entitled “Controlled Release Doxycycline,” was duly and lawfully issued by the USPTO on December 6, 2016. A true and correct copy of the ’031 Patent is attached hereto as Exhibit E.

DEFENDANTS’ SUPPLEMENT TO ANDA NO. 090134

28. On information and belief, Defendants have submitted or caused to be submitted the Supplement to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of Doxycycline Hyclate Delayed-Released Tablets, 60 mg and 120 mg, as purported generic versions of DORYX® MPC tablets containing 60 mg and 120 mg dosage strengths, respectively, prior to the expiration of the ’161 Patent, the ’652 Patent, the ’057 Patent, and the ’031 Patent.

29. On information and belief, FDA has not approved the Supplement.

30. On information and belief, on or about September 28, 2017, Teva mailed the Notice Letter. The Notice Letter represented that Actavis Elizabeth had submitted to FDA the Supplement and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Defendants' ANDA Products before the expiration of the patents listed in the Orange Book for DORYX® MPC. Hence, Defendants' purpose in submitting the Supplement is to manufacture and market Defendants' ANDA Products before the expiration of the '161 Patent, the '652 Patent, the '057 Patent, and the '031 Patent.

31. Teva's Notice Letter stated that the Paragraph IV certification in the Supplement alleges that no valid claim of the '161 Patent, the '652 Patent, the '057 Patent, and the '031 Patent will be infringed by the manufacture, importation, use, or sale of Defendants' ANDA Products.

32. Teva's Notice Letter contained "Actavis Elizabeth, LLC's Detailed Factual and Legal Basis for Its Paragraph IV Certification" (hereinafter, "Detailed Statement").

33. Actavis Elizabeth's Detailed Statement identified no theory of non-infringement for the '161 Patent, the '652 Patent, the '057 Patent, or the '031 Patent.

34. After receiving Teva's Notice Letter and accompanying purported Offer of Confidential Access ("OCA"), Plaintiff wrote to Teva in an effort to negotiate reasonable terms of access to the Supplement. The parties agreed on terms for a revised OCA on October 19, 2017. Plaintiff's outside counsel received the Supplement on October 23, 2017, pursuant to the revised OCA.

35. On information and belief, Defendants have assisted with and participated in the preparation and submission of the Supplement, have provided material support to the preparation

and submission of the Supplement, and intend to support the further prosecution of the Supplement.

36. On information and belief, if FDA approves the Supplement, Defendants will manufacture, offer for sale, or sell Defendants' ANDA Products, within the United States, including within the State of Delaware, or will import Defendants' ANDA Products into the United States, including the State of Delaware.

37. On information and belief, if FDA approves the Supplement, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of Defendants' ANDA Products.

38. This action is being brought within forty-five days of Plaintiff's receipt of the Notice Letter. Accordingly, Plaintiff is entitled to a thirty-month stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
INFRINGEMENT OF THE '161 PATENT

39. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 as if fully set forth herein.

40. On information and belief, Defendants have submitted or caused the submission of the Supplement to FDA, and are thereby continuing to seek FDA approval of the Supplement.

41. Plaintiff owns all rights, title, and interest in and to the '161 Patent.

42. As demonstrated below, Defendants have infringed at least one claim of the '161 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the '161 Patent.

43. On information and belief, at least one of Defendants' ANDA Products consists of a modified release preparation having one or more core elements.

44. On information and belief, at least one of Defendants' ANDA Products includes an active ingredient selected from the group consisting of the acid salts of doxycycline, tetracycline, oxytetracycline, minocycline, chlortetracycline, or demeclocycline.

45. On information and belief, at least one of Defendants' ANDA Products includes a modified release coating.

46. On information and belief, at least one of Defendants' ANDA Products includes a stabilising coat between a core element and its modified release coating.

47. On information and belief, upon *in vitro* dissolution testing of at least one of Defendants' ANDA Products, the amount of active ingredient released at any time on a post-storage dissolution profile is within 40 percentage points of the amount of active ingredient released at any time on a pre-storage dissolution profile.

48. On information and belief, for at least one of Defendants' ANDA Products, the amount of active ingredient released at the majority of time points on the post-storage dissolution profile is within 30 percentage points of the amount of active ingredient released at the same time on the pre-storage dissolution profile.

49. On information and belief, for at least one of Defendants' ANDA Products, the amount of active ingredient released at the majority of time points on the post-storage dissolution profile is within 20 percentage points of the amount of active ingredient released at the same time on the pre-storage dissolution profile.

50. On information and belief, for at least one of Defendants' ANDA Products, the amount of active ingredient released at the majority of time points on the post-storage dissolution

profile is within 10 percentage points of the amount of active ingredient released at the same time on the pre-storage dissolution profile.

51. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products is a delayed release coating.

52. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products is a delayed release coating suitable to release, in a pre-storage *in vitro* dissolution, 20% or less of the active ingredient in a pH of about 1.2 by 20 minutes.

53. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products is a delayed release coating suitable to release, in a pre-storage *in vitro* dissolution, at least 80% of the active ingredient in a pH of at least 5 by 60 minutes.

54. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products is a delayed release coating suitable to release, in a pre-storage *in vitro* dissolution, 10% or less of the active ingredient in a pH of about 1.2 by 20 minutes.

55. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products is a delayed release coating suitable to release, in a pre-storage *in vitro* dissolution, at least 90% of the active ingredient in a pH of at least 5 by 60 minutes.

56. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products is an enteric coating, a semi-enteric coating, a delayed release coating, a pulsed release coating, a mixture of enteric polymers, or a mixture of an enteric polymer with a water-permeable, water-swellable or water-soluble material.

57. On information and belief, a water-soluble or water-permeable material included in at least one of Defendants' ANDA Products is one or a mixture of hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone and polyethylene glycol.

58. On information and belief, a modified release coating included in at least one of Defendants' ANDA Products includes one or more of hydroxypropylmethyl cellulose phthalate, a pH dependent anionic methacrylate based polymer, or hydroxypropylmethyl cellulose acetate succinate.

59. On information and belief, a stabilising coat included in at least one of Defendants' ANDA Products is at least semi-permeable in aqueous media.

60. On information and belief, a stabilising coat included in at least one of Defendants' ANDA Products is one or a mixture of a water-soluble, water-swellable or water-permeable polymeric or monomeric material.

61. On information and belief, a stabilising coat included in at least one of Defendants' ANDA Products is one or a mixture of hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, polyethylene glycol, or a pH dependent anionic methacrylate based polymer.

62. On information and belief, an active ingredient included in at least one of Defendants' ANDA Products, upon administration in an immediate release form, normally causes nausea and gastric irritation.

63. On information and belief, at least one of Defendants' ANDA Products is provided as a plurality of coated core elements compressed to form a tablet.

64. On information and belief, the percentage of coated core elements in at least one of Defendants' ANDA Products that are provided as a plurality of coated elements compressed to form a tablet is in the range of 20 to 40% by weight of the total dosage weight.

65. On information and belief, the percentage of coated core elements in at least one of Defendants' ANDA Products that are provided as a plurality of coated elements compressed to form a tablet is in the range of 25 to 35% by weight of the total dosage weight.

66. On information and belief, the percentage of coated core elements in at least one of Defendants' ANDA Products that are provided as a plurality of coated elements compressed to form a tablet is about 30% by weight of the total dosage weight.

67. On information and belief, at least one of Defendants' ANDA Products includes a delayed release coating as a modified release coating and an acid salt of doxycycline as an active ingredient, and is provided as a plurality of coated core elements compressed to form a tablet.

68. On information and belief, at least one of Defendants' ANDA Products consists of a tablet for oral administration that is a modified release preparation including one or more coated core elements.

69. On information and belief, at least one of Defendants' ANDA Products includes an acid salt of doxycycline.

70. On information and belief, at least one of Defendants' ANDA Products includes a modified release coating.

71. On information and belief, at least one of Defendants' ANDA Products includes a stabilising coat provided between each core element and its modified release coating.

72. On information and belief, at least one of Defendants' ANDA Products consists of a pellet for use in a dosage form for oral administration that is a modified release preparation having one or more coated core elements.

73. On information and belief, at least one of Defendants' ANDA Products includes an active ingredient comprising an acid salt of doxycycline.

74. On information and belief, an active ingredient included in at least one of Defendants' ANDA Products is an acid salt of doxycycline.

75. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '161 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Supplement, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within the United States, or will import Defendants' ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '161 Patent.

76. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants' ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Products with a product label and product insert that will include instructions for using and administering Defendants' ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants' ANDA Products to directly infringe one or more claims of the '161 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '161 Patent and knowledge that they are encouraging infringement.

77. Defendants had actual and constructive notice of the '161 Patent prior to filing the Supplement, and were aware that the filing of the Supplement with the request for FDA approval prior to the expiration of the '161 Patent would constitute an act of infringement of the '161 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use,

offer for sale, or sale of Defendants' ANDA Products will not contribute to the infringement of and/or induce the infringement of the '161 Patent.

78. Actavis Elizabeth's Detailed Statement in the Notice Letter lacks any contention that Defendants' ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '161 Patent.

79. In addition, Defendants filed the Supplement without adequate justification for asserting the '161 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '161 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

80. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '161 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '161 PATENT

81. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–80 as if fully set forth herein.

82. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

83. On information and belief, if the Supplement is approved, Defendants' ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

84. On information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA Products in accordance with the labeling sought by the Supplement and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '161 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

85. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves the Supplement. Any such conduct before the '161 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '161 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

86. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '161 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

87. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

88. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '652 PATENT

89. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 as if fully set forth herein.

90. On information and belief, Defendants have submitted or caused the submission of the Supplement to FDA, and are thereby continuing to seek FDA approval of the Supplement.

91. Plaintiff owns all rights, title, and interest in and to the ’652 Patent.

92. As demonstrated below, Defendants have infringed at least one claim of the ’652 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the ’652 Patent.

93. On information and belief, at least one of Defendants’ ANDA Products consists of a plurality of modified release doxycycline pellets.

94. On information and belief, at least one of Defendants’ ANDA Products includes doxycycline.

95. On information and belief, at least one of Defendants’ ANDA Products includes a controlled release polymer composition disposed over doxycycline.

96. On information and belief, at least one of Defendants’ ANDA Products includes 60 mg or 120 mg of doxycycline.

97. On information and belief, at least one of Defendants’ ANDA Products releases less than 15% of the doxycycline at pH 1.2, and less than 40% of the doxycycline at pH 4.5 after 60 minutes, measured under USP <711> conditions.

98. On information and belief, for at least one of Defendants’ ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 625-1600 ng/ml.

99. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 1250-3200 ng/ml.

100. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 10000-24000 ng·hr/ml.

101. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 20000-48500 ng·hr/ml.

102. On information and belief, at least one of Defendants' ANDA Products includes a doxycycline-containing core.

103. On information and belief, at least one of Defendants' ANDA Products includes a controlled release polymer composition that is disposed as a layer over a doxycycline-containing core.

104. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA products includes a blend of an enteric polymer and a water-soluble polymer.

105. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA products includes a plasticizer.

106. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products consists of a blend of an enteric polymer, a water-soluble polymer, and a plasticizer.

107. On information and belief, an enteric polymer included in at least one of Defendants' ANDA Products is selected from a group consisting of hydroxypropyl methylcellulose phthalate, poly(methacrylic acid-co-ethyl acrylate), poly(methacrylic acid-co-methyl methacrylate), poly(methyl acrylate-co-methyl methacrylate-co-methacrylic acid), hydroxypropylmethyl cellulose acetate succinate, cellulose acetate succinate, polyvinyl acetate phthalate, shellac, cellulose acetate trimellitate, sodium alginate, and combinations thereof.

108. On information and belief, a water-soluble polymer included in at least one of Defendants' ANDA Products is selected from the group consisting of hydroxypropyl methylcellulose, methylcellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, polyethylene glycol, polyvinyl alcohol, and combinations thereof.

109. On information and belief, a plasticizer included in at least one of Defendants' ANDA Products is selected from the group consisting of citric acid esters, tartaric acid esters, glycerol, glycerol esters, phthalic acid esters, adipic acid esters, sebacic acid esters, polyethylene glycol esters, sorbitan esters, and combinations thereof.

110. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products consists of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose, and triethyl citrate.

111. On information and belief, for at least one of Defendants' ANDA Products including a controlled release polymer composition that consists of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose, and triethyl citrate, the ratio of

hydroxypropyl methylcellulose phthalate to hydroxypropyl methylcellulose ranges from 3.5:1 to 6:1.

112. On information and belief, at least one of Defendants' ANDA Products includes a stabilizing coating disposed between a doxycycline-containing core and a controlled release polymer composition layer.

113. On information and belief, a stabilizing coating included in at least one of Defendants' ANDA Products comprises a water-soluble polymer and talc.

114. On information and belief, at least one of Defendants' ANDA Products is orally administered to treat a skin condition in a patient.

115. On information and belief, at least one of Defendants' ANDA Products is administered to treat a skin condition selected from the group consisting of: a skin infection, rosacea, acne, papules, pustules, open comedo, closed comedo, or a combination thereof.

116. On information and belief, at least one of Defendants' ANDA Products can be administered once per day.

117. On information and belief, a controlled release polymer included in at least one of Defendants' ANDA Products includes a blend of an enteric polymer and a plasticizer.

118. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '652 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Supplement, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within the United States, or will import Defendants' ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '652 Patent.

119. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants' ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Products with a product label and product insert that will include instructions for using and administering Defendants' ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants' ANDA Products to directly infringe one or more claims of the '652 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '652 Patent and knowledge that they are encouraging infringement.

120. Defendants had actual and constructive notice of the '652 Patent prior to filing the Supplement, and were aware that the filing of the Supplement with the request for FDA approval prior to the expiration of the '652 Patent would constitute an act of infringement of the '652 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA Products will not contribute to the infringement of and/or induce the infringement of the '652 Patent.

121. Actavis Elizabeth's Detailed Statement in the Notice Letter lacks any contention that Defendants' ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '652 Patent.

122. In addition, Defendants filed the Supplement without adequate justification for asserting the '652 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA Products. Defendants' conduct in

certifying invalidity, unenforceability, and/or non-infringement with respect to the ’652 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

123. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’652 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’652 PATENT

124. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 and 89–123 as if fully set forth herein.

125. Plaintiff’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

126. On information and belief, if the Supplement is approved, Defendants’ ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

127. On information and belief, Defendants know that health care professionals or patients will use Defendants’ ANDA Products in accordance with the labeling sought by the Supplement and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the ’652 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

128. On information and belief, Defendants’ infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants’ ANDA Products complained of herein will begin immediately after FDA approves the Supplement. Any such

conduct before the ’652 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’652 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

129. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the ’652 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

130. Plaintiff will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

131. This case is exceptional, and Plaintiff is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE ’057 PATENT

132. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 as if fully set forth herein.

133. On information and belief, Defendants have submitted or caused the submission of the Supplement to FDA, and are thereby continuing to seek FDA approval of the Supplement.

134. Plaintiff owns all rights, title, and interest in and to the ’057 Patent.

135. As demonstrated below, Defendants have infringed at least one claim of the ’057 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the ’057 Patent.

136. On information and belief, at least one of Defendants' ANDA Products consists of a plurality of modified release doxycycline pellets.

137. On information and belief, at least one of Defendants' ANDA Products includes doxycycline.

138. On information and belief, at least one of Defendants' ANDA Products includes a controlled release polymer composition disposed over doxycycline.

139. On information and belief, at least one of Defendants' ANDA Products includes 60 or 120 mg of doxycycline.

140. On information and belief, at least one of Defendants' ANDA Products maintains doxycycline release levels measured under USP <711> conditions at pH 5 that provide a clinically effective plasma level of doxycycline.

141. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 625-1600 ng/ml.

142. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 1250-3200 ng/ml.

143. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 10000-24000 ng·hr/ml.

144. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 20000-48500 ng·hr/ml.

145. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least one of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

146. On information and belief, at least one of Defendants' ANDA Products maintains release levels measured under USP <711> conditions that are low at pH values up to pH 4.5.

147. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least two of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

148. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least three of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

149. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is at least four of the following: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

150. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline at pH 5 measured under USP <711> conditions is: 45% to 50% after 10 minutes; 55% to 65% at 20 minutes; 65% to 70% at 30 minutes; 70% to 75% at 45 minutes; and 75% to 80% at 60 minutes.

151. On information and belief, at least one of Defendants' ANDA Products includes a doxycycline-containing core.

152. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products is disposed as a layer over a doxycycline-containing core.

153. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products includes a blend of an enteric polymer and a water-soluble polymer.

154. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products includes a plasticizer.

155. On information and belief, a controlled release polymer composition included in at least on of Defendants' ANDA Products consists of a blend of an enteric polymer, a water-soluble polymer, and a plasticizer.

156. On information and belief, at least one of Defendants' ANDA Products includes a stabilizing coating disposed between a doxycycline-containing core and a controlled release polymer composition layer.

157. On information and belief, at least one of Defendants' ANDA Products is orally administered to treat a skin condition in a patient.

158. On information and belief, at least one of Defendants' ANDA Products is orally administered to treat at least one skin condition selected from the group consisting of: a skin infection, rosacea, acne, papules, pustules, open comedo, closed comedo, or a combination thereof.

159. On information and belief, at least one of Defendants' ANDA Products can be administered once per day.

160. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '057 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Supplement, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within the United States, or will import Defendants' ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '057 Patent.

161. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants' ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Products with a product label and product insert that will include instructions for using and administering Defendants' ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants' ANDA Products to directly infringe one or more claims of the '057 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '057 Patent and knowledge that they are encouraging infringement.

162. Defendants had actual and constructive notice of the ’057 Patent prior to filing the Supplement, and were aware that the filing of the Supplement with the request for FDA approval prior to the expiration of the ’057 Patent would constitute an act of infringement of the ’057 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA Products will not contribute to the infringement of and/or induce the infringement of the ’057 Patent.

163. Actavis Elizabeth’s Detailed Statement in the Notice Letter lacks any contention that Defendants’ ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the ’057 Patent.

164. In addition, Defendants filed the Supplement without adequate justification for asserting the ’057 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’057 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

165. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’057 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’057 PATENT

166. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 and 132–165 as if fully set forth herein.

167. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

168. On information and belief, if the Supplement is approved, Defendants' ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

169. On information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA Products in accordance with the labeling sought by the Supplement and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '057 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

170. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves the Supplement. Any such conduct before the '057 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '057 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

171. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '057 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

172. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

173. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE '031 PATENT

174. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 as if fully set forth herein.

175. On information and belief, Defendants have submitted or caused the submission of the Supplement to FDA, and are thereby continuing to seek FDA approval of the Supplement.

176. Plaintiff owns all rights, title, and interest in and to the '031 Patent.

177. As demonstrated below, Defendants have infringed at least one claim of the '031 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Supplement with a Paragraph IV certification and thereby seeking FDA approval of generic versions of DORYX® MPC prior to the expiration of the '031 Patent.

178. On information and belief, at least one of Defendants' ANDA Products consists of doxycycline combined with a controlled release composition.

179. On information and belief, at least one of Defendants' ANDA Products includes 60 or 120 mg of doxycycline.

180. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline measured under USP <711> conditions is at least one of: less than 48% at 15 minutes; less than 64% at 20 minutes; and less than 72% at 25 minutes.

181. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose under fasting conditions to

a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 625-1600 ng/ml.

182. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 1250-3200 ng/ml.

183. On information and belief, for at least one of Defendants' ANDA Products including 60 mg of doxycycline, after administration of a single dose to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 10000-24000 ng·hr/ml.

184. On information and belief, for at least one of Defendants' ANDA Products including 120 mg of doxycycline, after administration of a single dose to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 20000-48500 ng·hr/ml.

185. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline is at least one of: 30% to 48% at 15 minutes; 30% to 64% at 20 minutes; and 45% to 72% at 25 minutes.

186. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline is at least one of: 35% to 48% at 15 minutes; 40% to 64% at 20 minutes; and 50% to 72% at 25 minutes.

187. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 20 minutes ranges from 42% to 64%.

188. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 20 minutes ranges from 47% to 64%.

189. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes ranges from 58% to 72%.

190. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes ranges from 65% to 72%.

191. On information and belief, at least one of Defendants' ANDA Products includes a plurality of pellets.

192. On information and belief, a controlled release polymer composition included in at least one of Defendants' ANDA Products is disposed over doxycycline.

193. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes ranges from 60% to 72%.

194. On information and belief, for at least one of Defendants' ANDA Products, at pH 5.0 the normalized average release of doxycycline at 25 minutes is about 65%.

195. On information and belief, at least one of Defendants' ANDA Products can be administered once per day.

196. On information and belief, for at least one of Defendants' ANDA Products, the release of doxycycline is measured under USP <711> conditions with stirring at 50 RPM.

197. On information and belief, for at least one of Defendants' ANDA Products, after administration of a single dose under fasting conditions to a patient in need thereof, the average peak plasma doxycycline concentration is 80% to 125% of 10-27 ng/ml per mg of doxycycline administered.

198. On information and belief, for at least one of Defendants' ANDA Products, after administration of a single dose to a patient in need thereof, the average area under the curve (from zero to infinity) is 80% to 125% of 167-404 ng·hr/ml per mg of doxycycline administered.

199. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products would actively induce and/or contribute to infringement of the '031 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the Supplement, Defendants will make, use, offer to sell, or sell Defendants' ANDA Products within the United States, or will import Defendants' ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '031 Patent.

200. On information and belief, upon FDA approval of the Supplement, Defendants will market and distribute Defendants' ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Defendants' ANDA Products. On information and belief, Defendants will also knowingly and intentionally accompany Defendants' ANDA Products with a product label and product insert that will include instructions for using and administering Defendants' ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Defendants' ANDA Products to directly infringe one or more claims of the '031 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '031 Patent and knowledge that they are encouraging infringement.

201. Defendants had actual and constructive notice of the '031 Patent prior to filing the Supplement, and were aware that the filing of the Supplement with the request for FDA approval prior to the expiration of the '031 Patent would constitute an act of infringement of the '031

Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA Products will not contribute to the infringement of and/or induce the infringement of the '031 Patent.

202. Actavis Elizabeth's Detailed Statement in the Notice Letter lacks any contention that Defendants' ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '031 Patent.

203. In addition, Defendants filed the Supplement without adequate justification for asserting the '031 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '031 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

204. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '031 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '031 PATENT

205. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–38 and 174–204 as if fully set forth herein.

206. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

207. On information and belief, if the Supplement is approved, Defendants' ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

208. On information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA Products in accordance with the labeling sought by the Supplement and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '031 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f), and (g).

209. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products complained of herein will begin immediately after FDA approves the Supplement. Any such conduct before the '031 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '031 Patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

210. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '031 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

211. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

212. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Mayne respectfully requests the following relief:

(A) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Supplement to ANDA No. 090134 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products before the expiration of the '161 Patent was an act of infringement of one or more claims of the '161 Patent;

(B) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Supplement to ANDA No. 090134 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products before the expiration of the '652 Patent was an act of infringement of one or more claims of the '652 Patent;

(C) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Supplement to ANDA No. 090134 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products before the expiration of the '057 Patent was an act of infringement of one or more claims of the '057 Patent;

(D) The entry of a judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to FDA of the Supplement to ANDA No. 090134 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products before the expiration of the '031 Patent was an act of infringement of one or more claims of the '031 Patent;

(E) The entry of a declaratory judgment that under one or more of 35 U.S.C. § 271 (a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or

importation into, the United States of Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '161 Patent;

(F) The entry of a declaratory judgment that under one or more of 35 U.S.C. § 271 (a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '652 Patent;

(G) The entry of a declaratory judgment that under one or more of 35 U.S.C. § 271 (a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '057 Patent;

(H) The entry of a declaratory judgment that under one or more of 35 U.S.C. § 271 (a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '031 Patent;

(I) The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, using, offering for sale, or selling Defendants' ANDA Products within the United States, or importing Defendants' ANDA Products into the United States, until the expiration of the '161 Patent, the '652 Patent, the '057 Patent, and the '031 Patent;

(J) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Supplement to ANDA No. 090134 shall be no earlier than the last expiration date of any of the '161 Patent, the '652 Patent, the '057 Patent, and the '031 Patent, or

any later expiration of exclusivity for any of the ’161 Patent, the ’652 Patent, the ’057 Patent, and the ’031 Patent, including any extensions or regulatory exclusivities;

(K) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA Products, or any product that infringes the ’161 Patent, or induces or contributes to such conduct, prior to the expiration of the ’161 Patent;

(L) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA Products, or any product that infringes the ’652 Patent, or induces or contributes to such conduct, prior to the expiration of the ’652 Patent;

(M) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA Products, or any product that infringes the ’057 Patent, or induces or contributes to such conduct, prior to the expiration of the ’057 Patent;

(N) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA Products, or any product that infringes the ’031 Patent, or induces or contributes to such conduct, prior to the expiration of the ’031 Patent;

(O) The entry of judgment declaring that Defendants’ acts render this case an exceptional case, and awarding Plaintiff its attorneys’ fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(P) An award to Plaintiff of its costs and expenses in this action; and

(Q) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
Megan Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

George F. Pappas
Michael N. Kennedy
Chanson Chang
Hwa Young Jin
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

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